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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,182	08/31/2000	Paul D. Robbins	AP32573-A-A/072396.0203	4223

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BAKER & BOTTS  
30 ROCKEFELLER PLAZA  
NEW YORK, NY 10112

EXAMINER
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TIZIO, STEVEN C

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 12/07/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/653,182

Applicant(s)

ROBBINS ET AL.

Examiner

Steven C Tizio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.

### **DETAILED ACTION**

**Please note:** *In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is (703) 305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this pilot program. If you have any questions or suggestions please contact Jyothnsa Venkat, Ph.D., Supervisory Examiner, at Jyothnsa.Venkat@uspto.gov or 703-308-2439. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.*

### **Election/Restrictions**

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims **1-7**, drawn to the peptide of a particular amino acid sequence, classified in class 530, subclass 300.
  - II. Claims **8-22**, drawn to the peptide-cargo complex wherein the peptide has a particular amino acid sequence, classified in class 424, subclass 193.1.

- III. Claims **23-29**, drawn to the method for identifying peptides capable of cellular internalization of a linked cargo, classified in class 435, subclass 5 (bacterial vectors).
- IV. Claims **30-36**, drawn to the expression cassette that codes for a fusion protein comprising a leader sequence, protein of interest, and an internalizing peptide having a particular amino acid sequence, classified in class 435, subclass 6.
- V. Claim **37, 40-44**, drawn to the method for inducing synovial cell death comprising administering a peptide-cargo complex to said tumor cell, classified in class 530, subclass 300.
- VI. Claim **38, 40-44**, drawn to the method for inducing apoptosis in a tumor cell by administering a peptide-cargo complex, classified in class 530, subclass 300.
- VII. Claim **39, 40-44**, drawn to the method for reducing white blood cells in arthritic joints by administering a peptide-cargo complex, classified in class 530, subclass 300.
- VIII. Claims **45-47**, drawn to the method for internalizing a GST-fusion protein into a cell, classified in class 530, subclass 300.
- IX. Claims **48-50**, drawn to the kit for internalizing a GST-fusion protein into a cell, classified in class 530, subclass 300.

- X. Claims **51-56**, drawn to an immunogen comprising a peptide-cargo complex wherein the peptide consists of a particular amino acid sequence, classified in class 530, subclass 300.
- XI. Claims **57-59**, drawn to the method for eliciting an immune response by administering an immunogen comprising a peptide-cargo complex wherein the peptide consists of a particular amino acid sequence, classified in class 630, subclass 300.

2. The inventions are distinct, each from the other because of the following reasons:

3. **Groups I, II, IV, IX, and X** relate to different products (i.e., e.g., which have different chemical compositions, physical properties, biochemical activities, and biochemical uses) and thus represent separate and distinct inventions. **Group I** relates to a peptide of a particular amino acid sequence, **Group II** relates to a peptide-cargo complex wherein the peptide has a particular amino acid sequence and cargo attached, **Group IV** relates to an expression cassette that codes for a fusion protein, **Group IX** relates to a kit for internalizing a GST-fusion protein into a cell, and **Group X** relates to an immunogen comprising a peptide-cargo complex. Therefore, the groups that describe these products have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious

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another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics.

4. **Groups III, V, VI, VII, VIII, and XI** relate to different methods or processes (i.e., e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results) and thus represent separate and distinct inventions. **Group III** relates to the method for identifying peptides capable of cellular internalization of a linked cargo, **Group V** relates to the method for inducing synovial cell death by administering a peptide-cargo complex to the tumor cell, **Group VI** relates to the method for inducing apoptosis in a tumor cell by administering a peptide-cargo complex, **Group VII** relates to the method for reducing white blood cells in arthritic joints by administering a peptide-cargo complex, **Group VIII** relates to the method for internalizing a GST-fusion protein into a cell, and **Group XI** relates to the method for eliciting an immune response by administering an immunogen comprising a peptide-cargo complex. Therefore, the groups that describe these methods have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to

different inventions that have different distinguishing features and/or characteristics.

Each group will support separate patents.

5. Inventions related to the different products of **Groups I, II, IV, IX, and X** and the inventions related to the different methods of **Groups III, V, VI, VII, VIII, and XI** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions in the two subgroups, “product” and “methods” have different uses and functions.

6. Inventions of **Group I** (peptide) and of **Group II** (peptide-cargo complex) and **Group III** (method for identifying peptides capable of cellular internalization of a linked cargo) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a different peptide (**Group I**) or a different peptide-cargo complex (**Group II**) can be used to identify peptides capable of cellular internalization of a linked cargo. There are other combinations of peptide sequences and cargo constituents that can be used in the method of **Group III**.

7. Inventions of **Group II** (peptide-cargo complex) and **Groups V** (method for inducing synovial cell death), **VI** (method for inducing apoptosis), and **VII** (method for reducing white blood cells in arthritic joints) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptide-cargo complex of Group II can be used in either the methods of **Group V**, **Group VI**, or **Group VII**. Thus restriction between groups is proper.

8. Inventions of **Group IX** (kit for internalizing a GST-fusion protein) and **Group VIII** (the method of internalizing a GST-fusion protein into a cell) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the GST-fusion protein can be internalized into a cell via other methods, such as through recombinant DNA methods, protein engineering techniques, or genetic engineering techniques, in addition to using the kit of **Group IX**.

9. Inventions of **Group X** (immunogen comprising a peptide-cargo complex) and **Group XI** (the method for eliciting an immune response by administering the



immunogen comprising a peptide-cargo complex) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case an immune response can be elicited by other methods, such as tagging the cell with an antigen or a foreign protein, in addition to using the immunogen/peptide-cargo complex of **Group X**. In addition, there are a variety of immunogens that can be used to elicit an immune response; **Group X** does not specify a particular immunogen.

10. These inventions are distinct for the reasons above and have acquired a separate status in the art because of their recognized divergent subject matter and/or shown by their different classifications. While some of the aforementioned groups are classified under an identical class/sub-class, the corresponding non-patent literature search remains unaffected. Each of the identified groups may require different searches. For example, methods and products groups require different searches. Therefore, restriction for examination purposes as indicated is proper.

### **Election of Species**

11. This application contains claims directed to the following patentably distinct species of the claimed invention:

- a) If **Group I** is elected, applicants are requested to elect a single species of a peptide in **claim 1**.
- b) If **Group II** is elected, applicants are requested to elect a single species for each of the following:
  - (1) a single species of the peptide in the peptide-cargo complex in **claim 8**
  - (2) a single cargo species (polynucleotide, polypeptide, small molecule, virus, modified virus, viral vector, and a plasmid) in **claim 9**
  - (3) a single virus species (adenovirus, adeno-associated virus, herpes simplex virus, and retrovirus) in **claim 10**
  - (4) a single protein species (therapeutic proteins, suicide proteins, tumor suppressor proteins, transcription factors, kinase inhibitors, kinases, cell cycle regulatory proteins, apoptotic proteins, anti-apoptotic proteins, viral antigens, cellular antigens, differentiation factors, immortalization factors and toxins) in **claim 11**
  - (5) a single apoptotic protein species (p53, caspase-3, HSV thymidine kinase and an antimicrobial peptide) in **claim 19**
  - (6) a single antimicrobial peptide species (SEQ ID NO:22, SEQ ID NO:23) in **claim 20**.
- c) If **Group III** is elected, applicants are requested to elect a single cargo species (polynucleotide, polypeptide, small molecule, virus, modified virus, viral vector, and a plasmid) in **claim 29**.

- d) If **Group IV** is elected, applicants are requested to elect a single species for each of the following:
- (1) a single species of internalizing peptide in the expression cassette in **claim 30**
  - (2) a single species of leader sequence (I1-1ra, PTH, VP-22 and related sequences) in **claim 33**
  - (3) a single protein species (apoptotic protein, anti-apoptotic protein, cell cycle regulatory protein, transcription factor, suicide gene product, viral or tumor antigens, and cell proliferation factors) in **claim 34**.
- e) If **Group V** is elected, applicants are requested to elect a single species for each of the following:
- (1) a single species of peptide in **claim 40**
  - (2) a single species of apoptotic protein (p53, caspase-3, HSV thymidine kinase and an antimicrobial peptide) in **claim 42**
  - (4) a single species of antimicrobial peptide (SEQ ID NO:22, SEQ ID NO:23) in **claim 43**.
- f) If **Group VI** is elected, applicants are requested to elect a single species for each of the following:
- (1) a single species of peptide in **claim 40**
  - (2) a single species of apoptotic protein (p53, caspase-3, HSV thymidine kinase and an antimicrobial peptide) in **claim 42**

- (3) a single species of antimicrobial peptide (SEQ ID NO:22, SEQ ID NO:23) in **claim 43**.
- g) If **Group VII** is elected, applicants are requested to elect a single species for each of the following:
- (1) a single species of peptide in **claim 40**
  - (2) a single species of apoptotic protein (p53, caspase-3, HSV thymidine kinase and an antimicrobial peptide) in **claim 42**
  - (3) a single species of antimicrobial peptide (SEQ ID NO:22, SEQ ID NO:23) in **claim 43**.
- h) If **Group VIII** is elected, applicants are requested to elect a single species of peptide in **claim 46**.
- i) If **Group IX** is elected, applicants are requested to elect a single species of peptide in **claim 49**.
- j) If **Group X** is elected, applicants are requested to elect a single species for each of the following:
- (1) a single species of peptide in the peptide-cargo complex in **claim 51**
  - (2) a single cargo species (polynucleotide, polypeptide, protein, virus, modified virus, viral vector, and a plasmid) in **claim 54**
  - (3) a single HIV protein species (Gag, Pol, Env, Tat, Nef, Vpr, Vpv, Rev) in **claim 56**.
- k) If **Group XI** is elected, applicants are requested to elect a single peptide species in the peptide-cargo complex in **claim 57**.

12. Each of the species encompassed by the claimed invention represent patentably distinct subject matter. In the instant case, those species involve different methods and different products. Therefore, those species involve different patentability and enablement issues.

13. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **claims 2-7, 12-18, 21-28, 31-32, 35-39, 41, 44-45, 47-48, 50, 52-53, 55, and 58-59** generic.

14. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

15. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

16. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

17. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

19. Applicant is required to reply to the restriction requirement within 30 days of mailing this action. See MPEP 809.2(a).

### **Conclusion**

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Tizio whose telephone number is (703) 305-1903. The examiner can normally be reached on Monday through Friday from 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached at (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
**PADMASHRI PONNALURI**  
**PRIMARY EXAMINER**

Steven C. Tizio  
Patent Examiner  
Technology Center 1600  
AU 1627



# RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

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TO EXAMINER: Steven Tizio

ART UNIT: 1627

SERIAL NUMBER: [REDACTED] 09/653,182

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